



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

February 18, 2004

Buchanan Ingersoll Attorneys
1776 K Street, N.W.
Suite 800
Washington, District of Columbia 20006-2365

Dear Mr. Allera:

Your petition, submitted on behalf of Buchanan Ingersoll requesting the Food and Drug Administration to establish specific bioequivalence requirements for oral products containing oxandrolone because of several unique aspects of these drugs products, It was assigned docket number 2004P-0074/CP 1 and it was filed on 02/18/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management